K133304

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MAY 15 2014

510(k) Summary
Section 21 CFR 807.92

Submitter:	KLS Martin L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Jennifer Damato Director of Quality Mgt and Regulatory Affairs Phone: 800-625-1557 Fax: 904-641-7378
Date Prepared:	May 13, 2014
Trade Name:	RxG Distraction System
Common Name:	Resorbable Distractor
Classification:	Bone Plate Class II, 21 CFR 872.4760, Product Code JEY
Predicate Devices:	LactoSorb Distraction **(K030425, K002083)** Resorb-X G **(K112064)**, Zurich Distraction System **(K010139)**

Device Description:
The RxG Distraction System consists of implantable devices used to lengthen or increase the dimension of maxillary and mandibular bones through distraction osteogenesis. It is composed of multiple sizes and shapes of RxG footplates and a threaded drive screw connected to an activation arm. The device is positioned internally with the connected activation arm extending through the soft tissue for external activation. The RxG footplates are secured to the bone on either side of the osteotomy with SonicPins RxG. Distraction is achieved by turning the activation arm with the patient activation driver, causing the plates to separate. Various lengths of drive screws are available to achieve up to 30 mm of distraction. Upon completion of distraction and consolidation of the bone, the drive screw is detached from the RxG footplates and removed, while the RxG footplates and SonicPins RxG remain implanted and are resorbed in 12-14 months.

Indications for Use:
The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the midface and alveolar ridge.

The RxG Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the mandible in patients 2 years old or younger.

The RxG Distraction System is not intended for load-bearing applications in adult or adolescent populations.

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Characteristic	RxG Distraction System	LactoSorb Distraction	Resorb-X G	Zurich Distraction System
Indications for Use	The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the midface and alveolar ridge. The RxG Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the mandible in patients 2 years old or younger. The RxG Distraction System is not intended for load-bearing applications in adult or adolescent populations.	The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The Lorenz Resorbable Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) when correction of mandibular deficiencies or post-traumatic defects require gradual bone distraction patients two (2) years old or younger. The mid-face distractor is intended primarily for LeFort III osteotomies.	Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-loading bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction.	The Zurich Distraction System includes devices intended as a bone stabilizer and lengthening (and or transport) device when correction of congential deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, symphisis), mid-face, and cranial bones require gradual distraction.
Contraindications	1. Active infection 2. Foreign body sensitivity	1. Active infection 2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation. 3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection. 4. Patients, or parents/guardians of patients are unwilling or incapable of following postoperative care instructions. 5. Patients with bleeding disorders or poor wound healing. 6. Patients with metabolic disorders.	1. High-load regions in the absence of traditional rigid fixation 2. Active or latent infections 3. Patients in a bad general state of health or suffering from metabolic disorders	1. Active infection 2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections 3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions 4. Foreign body sensitivity – where material sensitivity is suspected, tests are to be made prior to implantation
Target Population	Pediatrics and Adults	Pediatrics and Adults	Adolescents and Adults	Pediatrics and Adults
Anatomical Sites	Oral, Mandibular and Maxillofacial Areas	Cranial, Oral, Mandibular and Maxillofacial Areas	Oral, Mandibular and Maxillofacial Areas	Cranial, Oral, Mandibular and Maxillofacial Areas

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Characteristic	RxG Distraction System	LactoSorb Distraction	Resorb-X G	Zurich Distraction System
Materials				
Bone Plates	85:15 PLLA/PGA	82:18 PLLA/PGA	85:15 PLLA/PGA	TI-6AL-4V or CP Titanium
Bone Pins/Screws	85:15 PLLA/PGA	82:18 PLLA/PGA	85:15 PLLA/PGA	TI-6AL-4V
Drive Screw	TI-6AL-4V or Stainless Steel	Stainless Steel	N/A	TI-6AL-4V
Activation Arm	TI-6AL-4V or Stainless Steel	TI-6AL-4V , Stainless Steel	N/A	TI-6AL-4V
Sterility	Provided Sterile (Gamma Radiation)	Provided Sterile (ETO)	Provided Sterile (Gamma Radiation)	Provided Non-Sterile (Steam)
Where used (hospital, home, ambulance, etc)	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals
Breakdown Products (Plates, Pins/Screws)	H_2O and CO_2	H_2O and CO_2	H_2O and CO_2	Not applicable
Resorption Time	12 - 14 months	12 months	12 - 14 months	Not applicable
Max. Distraction Distance				
Alveolar Ridge Distractor	25 mm	25 mm	N/A	15 mm
Midface Distractor	30 mm	40 mm	N/A	30 mm
Mandibular Distractor	30 mm	25 mm	N/A	30 mm
Plate Thickness	2 - 5 mm	2 - 5 mm	0.6 - 1.0 mm	0.6 mm
Cumulative Max. Plate Volume	7840 mm^3	Unknown	15876 mm^3	Not applicable
Pin/Screw Diameter	2.1 mm	1.5 – 2.5 mm	1.6 mm	1.5 mm
Pin/Screw Length	3 - 7 mm	6 - 9 mm	5 mm	3.5 - 6 mm

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Performance Testing:
Comparative mechanical testing was performed between the RxG distractor and the LactoSorb distractor. The devices were affixed to abutted sawbone blocks to simulate an osteotomy and placed in a waterbath of Ringers solution for 48 hrs. Distraction and consolidation were then simulated over a period of 52 days. Deformation measurements were taken at regular intervals. The results of the mechanical testing showed that the RxG Distractor is substantially equivalent to the predicate.

Pyrogenicity:
No claim of "pyrogen free" is made.

Conclusion:
The RxG Distraction System has the same intended use as the predicate, the LactoSorb Distractor. The performance testing results and similarities in technological characteristics do not raise new issues of safety or effectiveness and demonstrate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

KLS-Martin, LP
Jennifer Damato
Director of Quality Management and Regulatory Affairs
11201 Saint Johns Industrial Pkwy S
Jacksonville, FL 32246 US

Re: K133304
Trade/Device Name: RxG Distraction System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: April 14, 2014
Received: April 17, 2014

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

SECTION 4

510(k) Number (if known): K133304

Device Name: RxG Distraction System

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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